

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family
(see Serial No.: 08/182,183; filed May 23, 1994; Docket No.:S-225E)

37 C.F.R. §5.25

PETITION FOR RETROACTIVE LICENSE UNDER 35 U.S.C. §184

Assistant Commissioner for Patents

Washington, D.C. 20231

Attention: Licensing and Review

1. Petition

It is respectfully requested that this petition for license for foreign filing be granted retroactively under the provisions of 37 C.F.R. §5.25. This petition is in accordance with 37 C.F.R. §5.13 for the foreign filing of the subject matter attached hereto, for which no corresponding U.S. application existed at the time a patent application was filed abroad.

Applicants request the grant of a retroactive foreign filing license for the material filed abroad as described in paragraph 4, below. The material was filed abroad through error and without deceptive intent, and the foreign applications do not disclose an invention within the scope of 35 U.S.C. §181.

Applicants request the date of the license to be September 9, 1992 -- the date on which the material was sent to foreign associates for filing abroad.

2. Previous Licenses

Attached to this petition are copies of the filing receipts/foreign filing licenses issued on this invention before a patent application was filed abroad. The following table summarizes this information for the members of this case family.

| <u>Application Number</u> | <u>Docket Number</u> | <u>Filing Date</u> | <u>Foreign Filing License</u> |
|-------------------------------|----------------------|-----------------------|------------------------------------|
| 07/764,685 (now abandoned) | S-225 | September 20, 1991 | not indicated on filing receipt |
| 07/774,109 (now abandoned) | S-225A | October 8, 1991 | no filing receipt received |
| 07/788,423 (now abandoned) | S-225B | November 6, 1991 | granted January 28, 1992 |
| 07/855,413 (now abandoned) | S-225C | March 19, 1992 | not indicated on filing receipt |

3. Identification of Pending U.S. Applications

Title of invention: Glial Cell Line-Derived Neurotrophic Factor

Inventors: Susan Bektesh, Franklin D. Collins, Daniel H. Doherty, Leu-Fen H. Lin and Jack Lile

United States Application Number 08/182,183 (S-225E) is a 35 U.S.C. §371 filing of PCT/US92/07888 filed September 17, 1992. This application corresponds to the applications filed abroad in the non-PCT countries. The application has also been divided into the following cases.

| <u>Application Number</u> | <u>Docket Number</u> | <u>Filing Date</u> | <u>Foreign Filing License Granted</u> |
|---------------------------|----------------------|--------------------|---|
| 08/182,183 | S-225E | May 23, 1994 | August 1, 1994 |
| 08/451,374 | S-225H | May 26, 1995 | June 20, 1995 |
| 08/452,229 | S-225I | May 26, 1995 | March 5, 1997 |
| 08/452,242 | S-225J | May 26, 1995 | July 13, 1995 |
| 08/453,176 | S-225K | May 30, 1995 | June 22, 1995 |
| 08/453,183 | S-225G | May 30, 1995 | July 13, 1995 |

A copy of the filing receipt for Application No. 08/182,183 (S-225E) is attached. As illustrated by the grant of foreign filing licenses for each of the currently pending cases, the information in the PCT/foreign filings did not disclose an invention within the scope of 35

U.S.C. §181. The information was not under a secrecy order at the time it was filed abroad, it is not currently under a secrecy order and it has never been under a secrecy order.

4. Material Filed Abroad Without a License

In accordance with 37 C.F.R. §5.13 a legible copy of the material upon which a license is requested accompanies this petition. The material corresponds to the subject matter of the WO 93/06116 publication (PCT/US92/07888) filed September 17, 1992. The material was filed abroad in the countries disclosed in paragraph 5, below.

The information contained in the foreign filings included subject matter not found in Application No. 07/788,423 (S-225B) for which a foreign filing license had been granted. To facilitate the identification of the information filed abroad that was not included in S-225B, the following summary is provided:

- corrections of typographical and grammatical errors
- Example 1 -- further information concerning lack of enhancement of serotonin uptake by serotonergic neurons
- Example 2 -- further information concerning the nucleotide sequence encoding the first 50 amino acids of leader (pre-pro) sequence
- Example 6 -- a protein refolding process and information concerning an updated method of enhancing E. coli production
- Figures 22-28 concerning the above
- further information concerning uses for GDNF
 - Example 7 manufacture of antibodies -- using known techniques
 - Example 8 encapsulation and implantation of GDNF producing cells -- using known techniques

5. Listing of Foreign Countries and Dates of Filing

With respect to the material for which a retroactive license is requested, the following table provides (1) a listing of each of the foreign countries in which the unlicensed patent application material was filed, and (2) the dates on which the material was filed in each country.

| <u>Country</u> | <u>Patent/Application Number</u> | <u>Filing Date</u> |
|----------------|--------------------------------------|--------------------|
| Bahamas | 1053 | September 18, 1992 |
| Israel | 103223 | September 18, 1992 |
| Mexico | 92 5293 | September 17, 1992 |
| New Zealand | 244392 | September 18, 1992 |
| Philippines | 44956 | September 18, 1992 |
| South Africa | 92/7159 | September 18, 1992 |
| Taiwan | 81108487 | October 23, 1992 |
| Portugal | 100879 | September 18, 1992 |

Applicants request the date of the retroactive license to be September 9, 1992 -- the date on which the material was sent to foreign counsel to prepare the foreign applications.

The application was also filed on 17 September 1992 for the following countries by means of the PCT application: European Patent Office (Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, Great Britain, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Sweden), Australia, Canada, Finland, Hungary, Japan, Norway, Republic of Korea, United States, Singapore and Georgia. At the time the PCT application was filed, the application transmittal letter included a "Request for a Foreign Transmittal License" (see copy attached, PTO-1382 item 5). The "Notification of the International Application Number and of the International Filing Date" (copy attached, form PCT/RO/105) notified Applicant that the record copy of the international application was transmitted to the International Bureau on 08 October 1992 and that a foreign filing license was not required.

In the event that it was not clear to the Receiving Office that the PCT application contained information which was not included in the parent applications, this petition further includes a request to extend the license to those countries designated in the PCT application filing.

6. Verified Statement

Attached hereto are verified statements of fact (declarations) by Applicants' current representative Daniel R. Curry and Applicants' former representative Barry J. Swanson who represented Applicants at the time the material was filed abroad. In accordance with 37 C.F.R. §5.25(a)(3)(i)-(iii), the statements provide:

- (i) a confirmation that the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order,
- (ii) a confirmation that the license has been diligently sought after discovery of the proscribed foreign filing, and
- (iii) an explanation of why the material was filed abroad through error and without deceptive intent without the required license under §5.11 first having been obtained.

As described above, the subject matter in question was not under a secrecy order at the time it was filed abroad and it is not currently under a secrecy order. The declaration of Daniel R. Curry further confirms that the discovery of the proscribed foreign filing was identified by Applicants' current representative on June 4, 1997 while reviewing the case file of Serial No. 08/452,242 (S-225J) following the receipt of the notice of allowance for that case. The license has been diligently sought with the filing of this petition.

The showing of facts of action through error and without deceptive intent is described in the declaration of Barry J. Swanson. The error resulted in the foreign filing of the information without benefit of a granted foreign filing license and prior to six months following the filing of a corresponding application in the PTO.

7. Fee (37 C.F.R. §1.17(h))

In accordance with 37 C.F.R. §5.25(a)(4), the fee for this petition for retroactive license is paid by charging Deposit Account No. 01-0519 in the name of Amgen Inc. in the amount of \$130.00, the required fee under §1.17(h). The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 01-0519. An original and two copies are enclosed.

A duplicate copy of this petition and attachments is provided. It is requested that the duplicate copy of this petition be returned with the license.

When the license is ready, please notify our agent, Charles E. Van Horn of Finnegan,

Henderson, Farabow, Garrett & Dunner, L.L.P., at phone number (202) 408-4072.

Respectfully submitted,

Daniel R. Curry

Daniel R. Curry
Attorney for Applicants
Registration No: 32,727
Phone: (805) 447-8102
Date: July 9, 1997

Please send all future correspondence to:

U.S. Patent Operations/DRC
M/S 10-1-B
AMGEN INC.
Amgen Center
1840 Dehavilland Drive
Thousand Oaks, California 91320-1789

FILING RECEIPT



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL |
|---------------|-------------|--------------|---------------|---------------------|-------|--------|--------|
| 07/764,685 | 09/20/91 | 1809 | \$1,630.00 | SYNE-220 | 20 | 22 | 17 |

BARRY J. SWANSON
BEATON AND SWANSON
4582 S. ULSTER ST. PKWY., #403
DENVER, CO 80237

Receipt is acknowledged of the patent application identified herein. It will be considered in its order and you will be notified as to the examination thereof. Be sure to give the U.S. SERIAL NUMBER, DATE OF FILING, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this transmittal.

Applicant(s)

LEU-FEN H. LIN, BOULDER, CO; FRANKLIN D. COLLINS,
BOULDER, CO; DANIEL H. DOHERTY, BOULDER, CO.

TITLE
GLIAL DERIVED NEUROTROPHIC FACTOR

PRELIMINARY CLASS: 530

FILING RECEIPT



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL |
|---------------|-------------|--------------|---------------|---------------------|-------|--------|--------|
| 07/788,423 | 11/06/91 | 1803 | \$1,840.00 | SYNE-225C2 | 24 | 44 | 12 |

BARRY J. SWANSON
BEATON & SWANSON
4582 S. ULSTER STREET PARKWAY
SUITE 403
DENVER, CO 80237

Receipt is acknowledged of the patent application identified herein. It will be considered in its order and you will be notified as to the examination thereof. Be sure to give the U.S. SERIAL NUMBER, DATE OF FILING, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this transmittal.

Applicant(s)

LEU-FEN H. LIN, BOULDER, CO; FRANKLIN D. COLLINS,
BOULDER, CO; DANIEL H. DOHERTY, BOULDER, CO; JACK
LILE, BOULDER, CO; SUSAN BEKTESH, BOULDER, CO.

CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A CIP OF 07/774,109 10/08/91
AND A CIP OF 07/764,685 09/20/91

FOREIGN FILING LICENSE GRANTED 01/28/92

TITLE

GLIAL DERIVED NEUROTROPHIC FACTOR

PRELIMINARY CLASS: 514

FILING RECEIPT



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| SERIAL NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL |
|---------------|-------------|--------------|---------------|---------------------|-------|--------|--------|
| 07/855,413 | 03/19/92 | 1804 | \$2,248.00 | SYNE-225C3 | 31 | 59 | 12 |

BARRY J. SWANSON
BEATON & SWANSON
4582 S. ULSTER ST. PKWY., SUITE 403
DENVER, CO 80237

Receipt is acknowledged of the patent application identified herein. It will be considered in its order and you will be notified as to the examination thereof. Be sure to give the U.S. SERIAL NUMBER, DATE OF FILING, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this transmittal.

Applicant(s)

LEU-FEN H. LIN, BOULDER, CO; FRANKLIN D. COLLINS,
BOULDER, CO; DANIEL H. DOHERTY, BOULDER, CO; JACK
LILE, BOULDER, CO; SUSAN BEKTESH, BOULDER, CO.

CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A CIP OF 07/788,423 11/06/91
AND A CIP OF 07/774,109 10/08/91
AND A CIP OF 07/764,685 09/20/91

TITLE
GLIAL DERIVED NEUROTROPHIC FACTOR

PRELIMINARY CLASS: 435

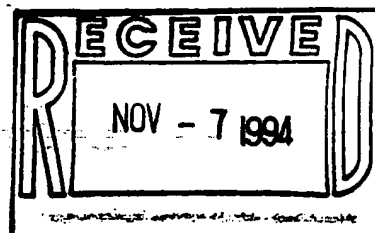
FILING RECEIPT
CORRECTED



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NUMBER | FILING DATE | GRP ART UNIT | FIL FEE REC'D | ATTORNEY DOCKET NO. | DRWGS | TOT CL | IND CL |
|--------------------|-------------|--------------|---------------|---------------------|-------|--------|--------|
| 08/182,183 | 05/23/94 | 1812 | \$2,846.00 | SYNE225/C4-U | 30 | 74 | 15 |

SWANSON & BRATSCUN L L C
SUITE 200
8400 E PRENTICE AVENUE
ENGLEWOOD CO 80111



Receipt is acknowledged of this patent application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Application Processing Division's Customer Connection Branch within 10 days of receipt. Please provide a copy of the Filing Receipt with the changes noted thereon.

Applicant(s)

LEU-FEN H. LIN, BOULDER, CO; FRANKLIN D. COLLINS,
AGOURA HILLS, CA; DANIEL H. DOHERTY, BOULDER, CO; JACK
LILE, NEDERLAND, CO; SUSAN BEKTESH, BOULDER, CO.

CONTINUING DATA AS CLAIMED BY APPLICANT-

THIS APPLN IS A 371 OF PCT/US92/07888 09/17/92

FOREIGN/PCT APPLICATIONS-PCT

PCT/US92/07888 09/17/92

FOREIGN FILING LICENSE GRANTED 08/01/94

TITLE

GLIAL DERIVED NEUROTROPHIC FACTOR

PRELIMINARY CLASS: 530

| | |
|---|---|
| PCT INTERNATIONAL APPLICATION TRANSMITTAL LETTER | DATE <u>September 17, 1992</u> |
| REGARDING THE INTERNATIONAL APPLICATION OF <u>Syntex-Synergen Neuroscience Joint Venture</u> | DOCKET OR REFERENCE NUMBER <u>SYN225/PCT</u> |
| ENTITLED <u>GLIAL DERIVED NEUROTROPHIC FACTOR</u> | |

Certification under 37 CFR 1.10 (if applicable)

GB58481752XUS

"Express Mail" mailing number

September 17, 1992
Date of deposit

I hereby certify that this application is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20211.

Barry J. Swanson

(Typed or printed name of person
mailing application)

Barry J. Swanson
(Signature of person mailing
application)

To the United States Receiving Office (RO/US):

Accompanying this transmittal letter is the above-identified International application, including a completed Request form (PCT/RO/101). Please process the application according to the provisions of the Patent Cooperation Treaty.

The following requests are made of the RO/US:

1. ☒ **PREPARATION AND TRANSMITTAL OF CERTIFIED COPY OF PRIORITY DOCUMENTS**—Please prepare and transmit to the International Bureau a certified copy of the United States origin priority documents identified in Box VI of the Request form (37 CFR 1.451).

To cover the cost of copy preparation and certification (37 CFR 1.19(a)(3) and (b)(1)),

☒ a (check) (money order) in the amount of \$ 48.00 is attached to this transmittal letter.

☐ the RO/US is hereby authorized to charge the following deposit account no.: _____

2. ☒ **CHOICE OF INTERNATIONAL SEARCHING AUTHORITY**—It is requested that the International Search be performed by the following International Searching Authority:

☒ United States Patent and Trademark Office (ISA/US)

☐ European Patent Office (ISA/EP)

The appropriate Search fee for the above-named Authority is indicated on the Fee Calculation Sheet (PCT/RO/101 Annex).

3. ☐ **SUPPLEMENTAL SEARCH FEES (ONLY WHEN ISA/US CONDUCTS THE INTERNATIONAL SEARCH)**—Please charge any Supplemental Search fees that may be required by the United States International Searching Authority (ISA/US) to deposit account no.: _____

I understand that this authorization is subject to my oral confirmation thereof in each instance and that it in no way limits my right to object or request a refund against payment of the Supplemental Search fee, but is merely an administrative aid to ensure that the ISA/US may timely recognize the Search Report.

NOTE: SUPPLEMENTAL SEARCH FEES FOR ISA/EP ARE PAYABLE DIRECTLY TO THE EUROPEAN PATENT OFFICE

4. ☐ **DISCLOSURE INFORMATION**—In order to assist in screening the accompanying International application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied:

A. ☐ There is no prior filed application relating to this invention.

B. ☐ There is a prior application, serial number _____ filed on _____ which contains subject matter that is

1. ☐ substantially identical to that of the accompanying International application.

2. ☐ less than that of the accompanying International application. The additional subject matter of the International application appears on page(s) and line(s) _____

3. ☐ more than that of the accompanying International application.

C. ☒ Disclosure information cannot be covered by the language of Points 4A or 4B above due to the involvement of several prior applications or for other reasons. A separate sheet of which the disclosure information is explained is attached to this transmittal letter. See Box VI of the Request Form

5. ☒ **REQUEST FOR FOREIGN TRANSMITTAL LICENSE**—According to the provisions of 35 U.S.C. 184 and 37 CFR 5.11, a license to transmit the accompanying International application to foreign agencies or international authorities is hereby requested.

| | |
|--|---|
| SIGNER IS THE <input type="checkbox"/> APPLICANT <input type="checkbox"/> COMMON REPRESENTATIVE <input checked="" type="checkbox"/> (ATTORNEY) AGENT REG NO. <u>33,215</u> | NAME OF SIGNER (typed) <u>Barry J. Swanson</u> SIGNATURE <u>Barry J. Swanson</u> |
|--|---|

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

| | | | |
|---|---|--|--|
| To: BARRY J. SWANSON BEATON & SWANSON, P.C. 4582 S. ULSTER ST. PARKWAY, SUITE 403 DENVER, COLORADO 80237 | | <h2 style="margin: 0;">PCT</h2> NOTIFICATION OF THE INTERNATIONAL APPLICATION NUMBER AND OF THE INTERNATIONAL FILING DATE (PCT Rule 20.5(c)) | |
| Applicant's or agent's file reference SYN 225/PCT | | IMPORTANT NOTIFICATION | |
| International application No. PCT/US92/07888 | International filing date (day/month/year) 17 SEP 92 | Priority date (day/month/year) 20 SEP 91 | |
| Applicant SYNTEX-SYNERGEN NEUROSCIENCE JOINT VENTURE | | | |
| Title of the invention GLIAL DERIVED NEUROTROPHIC FACTOR | | | |

1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.

2. The applicant is further notified that the record copy of the international application:

- ☒ was transmitted to the International Bureau on 08 OCT 1992
- ☐ has not yet been transmitted to the International Bureau for the reason indicated below and a copy of this notification has been sent to the International Bureau*:
- ☐ because the necessary national security clearance has not yet been obtained.
☐ because (reason to be specified):

**FOREIGN FILING LICENSE
NOT REQUIRED 37 CFR 5.11**

* The International Bureau monitors the transmittal of the record copy by the receiving Office and will notify the applicant (with Form PCT/IB/301) of its receipt. Should the record copy not have been received by the expiration of 14 months from the priority date, the International Bureau will notify the applicant (Rule 22.1(c)).

| | |
|--|---|
| Name and mailing address of the receiving Office COMMISSIONER OF PATENTS AND TRADEMARKS Box PCT Washington, D.C. 20231 Facsimile No. | Authorized officer Telephone No. |
|--|---|

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family
(see Serial No.: 08/182,183; filed May 23, 1994; Docket No.:S-225E)

**DECLARATION REGARDING PETITION FOR RETROACTIVE LICENSE
UNDER 35 U.S.C. §184 (37 C.F.R. §5.25)**

Assistant Commissioner of Patents

Washington, D. C. 20231

Attention: Licensing and Review

Sir:

Declarant

I, Daniel R. Curry (Declarant), am the current Attorney for Applicant of this family of applications.

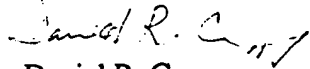
Statement

The discovery of the proscribed foreign filing was identified by Declarant on June 4, 1997 while reviewing the case file of Serial No. 08/452,242 (S-225J) following receipt of the notice of allowance for that case. The license has been diligently sought with the determination of facts concerning the foreign filing and the filing of the accompanying petition for a retroactive license.

Declarant further states that, upon a review of the case files for the affected applications and parent applications, the subject matter in question was not under a secrecy order at the time it was filed abroad, and that it is not currently under a secrecy order. In addition, the record indicates, by the grant of license for Application Serial No. 08/182,183 (S-225-E) which is the §371 filing of the PCT application which was filed abroad, that the license would have been granted if a petition had been made prior to the foreign filing.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Daniel R. Curry
Attorney for Applicant
Registration No: 32,727

AMGEN INC.
Amgen Center
1840 Dehavilland Drive
Thousand Oaks, California 91320-1789
Phone: (805) 447-8102

Date: July 9, 1997

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family
(see Serial No.: 08/182,183; filed May 23, 1994; Docket No.:S-225E)

**DECLARATION REGARDING PETITION FOR RETROACTIVE LICENSE
UNDER 35 U.S.C. §184 (37 C.F.R. §5.25)**

Assistant Commissioner of Patents

Washington, D. C. 20231

Attention: Licensing and Review

Sir:

Declarant

I, Barry J. Swanson (Declarant), am the former Attorney for Applicant of this family of applications.

Statement

As local counsel for Applicants at the time of the foreign filings described in the accompanying petition for retroactive foreign filing license, Declarant handled patent matters concerning the cases in the designated countries in conjunction with foreign counsel.

The application prepared for the PCT filing, which application was also used in the national filings described in the Petition (paragraph 5), included the following information which was not contained in Application No. 07/788,423 (S-225B) for which a foreign filing license had been granted:

- Example 1 -- further information concerning lack of enhancement of serotonin uptake by serotonergic neurons
- Example 2 -- further information concerning the nucleotide sequence encoding the first 50 amino acids of leader (pre-pro) sequence

- Example 6 -- a protein refolding process and information concerning an updated method of enhancing E. coli production
- Figures 22-28 illustrating data concerning the above
- further information concerning uses for GDNF
 - Example 7 manufacture of antibodies -- using known techniques
 - Example 8 encapsulation and implantation of GDNF producing cells -- using known techniques

This supplemental information to Examples 1, 2 and 6 was provided to describe the latest information concerning neuron populations affected or not affected by the GDNF proteins, further information on the sequencing of the nucleotides encoding the leader sequence of the GDNF proteins, and the latest best mode information concerning E. coli production of the proteins. The supplemental information exemplified by Example 7 concerned the latest information involving the production of anti-GDNF antibodies using the GDNF proteins described in the parent applications. The supplemental information exemplified by Example 8 concerned the envisioned use of encapsulated and implanted GDNF producing cells as based on teachings in the art further described on page 42, line 9 through page 43, line 11. This information was included in the PCT filing because the filing also designated the United States.

Declarant's general practice was to obtain the grant of a foreign filing license prior to filing an application outside the United States or to have the parent application on file for a period of not less than six months prior to the foreign filing. Due to the unique circumstances of the present case, however, the grant of a foreign filing license was overlooked. The unique circumstances included the fact that the parent applications were among the first patent applications assigned to a newly formed venture, the Syntex-Synergen Neuroscience Joint Venture.

The joint venture was formed in February of 1990 by Syntex (U.S.A.), Inc. of Palo Alto, California and Synergen, Inc. of Boulder, Colorado. The parent applications were the first patent applications filed by the joint venture, and the foreign cases involved in the accompanying petition were the first foreign applications filed by Declarant on behalf of the joint venture. Declarant was working closely with in-house patent counsel at both Syntex and Synergen in the preparation and filing of the foreign applications. The joint venture, however, had no defined procedures or checklists for confirming that all formalities and filing requirements were met. Thus, no counsel was identified as responsible for a final determination that all filing requirements, including foreign filing requirements, had been met. As a result, Declarant failed to consider whether a foreign filing license had been obtained for the application that was foreign filed.

In addition, the present case was unique in the number of parent cases involved. As described in the accompanying petition, a foreign filing license had been granted for the third

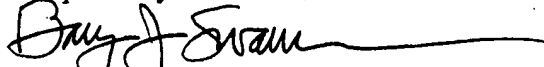
application in the series, and it was not typical in my office to have more than a single parent application involved in a foreign filing. Moreover, supplemental information for inclusion in the foreign filed application was received only a few weeks prior to the one year deadline for foreign filing. This further deviated from the norm as typically there were no continuation in part filings made to cases more than six months after the earliest filing date. The numerous parent cases and the late submission of information from the joint venture also led to Declarant's failure to consider whether a foreign filing license had been obtained prior to forwarding materials to foreign counsel for filing.

As a result of these circumstances, Declarant mistakenly overlooked the need to obtain a further foreign filing license (in addition to that granted for Application No. 07/788,423 (S-225B)) due to the inclusion of the supplemental information. Had Declarant considered the need for an additional foreign filing license grant, Declarant would have filed a petition for an expedited license. The mistake, however, was an error through overlooking the need for any additional license grant. The foreign filing was not performed with any deceptive intent.

Thus, Declarant as counsel for Applicants at the time of the foreign filings verifies that there was no plan or design to circumvent the statutes in question by providing the material to foreign counsel for filing abroad or by performing the foreign filings. The failure to obtain a foreign filing license prior to filing abroad was through error and without deceptive intent.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,



Barry J. Swanson

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Date: July 8, 1997

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Lin, et al.

For: GLIAL CELL LINE-DERIVED NEUROTROPHIC FACTOR

Docket No.: S-225 Case Family
(see Serial No.: 08/182,183; filed May 23, 1994; Docket No.:S-225E)

**DECLARATION REGARDING PETITION FOR RETROACTIVE LICENSE
UNDER 35 U.S.C. §184 (37 C.F.R. §5.25)**

Assistant Commissioner of Patents

Washington, D. C. 20231

Attention: Licensing and Review

Sir:

Declarant

I, Barry J. Swanson (Declarant), am the former Attorney for Applicant of this family of applications.

Statement

As local counsel for Applicants at the time of the foreign filings described in the accompanying petition for retroactive foreign filing license, Declarant handled patent matters concerning the cases in the designated countries in conjunction with foreign counsel.

The application prepared for the PCT filing, which application was also used in the national filings described in the Petition (paragraph 5), included the following information which was not contained in Application No. 07/788,423 (S-225B) for which a foreign filing license had been granted:

- Example 1 -- further information concerning lack of enhancement of serotonin uptake by serotonergic neurons
- Example 2 -- further information concerning the nucleotide sequence encoding the first 50 amino acids of leader (pre-pro) sequence

- Example 6 -- a protein refolding process and information concerning an updated method of enhancing E. coli production
- Figures 22-28 illustrating data concerning the above
- further information concerning uses for GDNF
 - Example 7 manufacture of antibodies -- using known techniques
 - Example 8 encapsulation and implantation of GDNF producing cells -- using known techniques

This supplemental information to Examples 1, 2 and 6 was provided to describe the latest information concerning neuron populations affected or not affected by the GDNF proteins, further information on the sequencing of the nucleotides encoding the leader sequence of the GDNF proteins, and the latest best mode information concerning E. coli production of the proteins. The supplemental information exemplified by Example 7 concerned the latest information involving the production of anti-GDNF antibodies using the GDNF proteins described in the parent applications. The supplemental information exemplified by Example 8 concerned the envisioned use of encapsulated and implanted GDNF producing cells as based on teachings in the art further described on page 42, line 9 through page 43, line 11. This information was included in the PCT filing because the filing also designated the United States.

Declarant's general practice was to obtain the grant of a foreign filing license prior to filing an application outside the United States or to have the parent application on file for a period of not less than six months prior to the foreign filing. Due to the unique circumstances of the present case, however, the grant of a foreign filing license was overlooked. The unique circumstances included the fact that the parent applications were among the first patent applications assigned to a newly formed venture, the Syntex-Synergen Neuroscience Joint Venture.

The joint venture was formed in February of 1990 by Syntex (U.S.A.), Inc. of Palo Alto, California and Synergen, Inc. of Boulder, Colorado. The parent applications were the first patent applications filed by the joint venture, and the foreign cases involved in the accompanying petition were the first foreign applications filed by Declarant on behalf of the joint venture. Declarant was working closely with in-house patent counsel at both Syntex and Synergen in the preparation and filing of the foreign applications. The joint venture, however, had no defined procedures or checklists for confirming that all formalities and filing requirements were met. Thus, no counsel was identified as responsible for a final determination that all filing requirements, including foreign filing requirements, had been met. As a result, Declarant failed to consider whether a foreign filing license had been obtained for the application that was foreign filed.

In addition, the present case was unique in the number of parent cases involved. As described in the accompanying petition, a foreign filing license had been granted for the third

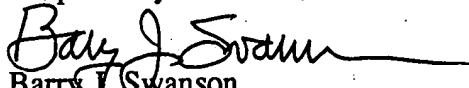
application in the series, and it was not typical in my office to have more than a single parent application involved in a foreign filing. Moreover, supplemental information for inclusion in the foreign filed application was received only a few weeks prior to the one year deadline for foreign filing. This further deviated from the norm as typically there were no continuation in part filings made to cases more than six months after the earliest filing date. The numerous parent cases and the late submission of information from the joint venture also led to Declarant's failure to consider whether a foreign filing license had been obtained prior to forwarding materials to foreign counsel for filing.

As a result of these circumstances, Declarant mistakenly overlooked the need to obtain a further foreign filing license (in addition to that granted for Application No. 07/788,423 (S-225B)) due to the inclusion of the supplemental information. Had Declarant considered the need for an additional foreign filing license grant, Declarant would have filed a petition for an expedited license. The mistake, however, was an error through overlooking the need for any additional license grant. The foreign filing was not performed with any deceptive intent.

Thus, Declarant as counsel for Applicants at the time of the foreign filings verifies that there was no plan or design to circumvent the statutes in question by providing the material to foreign counsel for filing abroad or by performing the foreign filings. The failure to obtain a foreign filing license prior to filing abroad was through error and without deceptive intent.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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